

## **Remarks/Arguments**

### **Status of Claims**

Claims 2-6, 8 and 9 are pending in the application and are under substantive examination. Claims 2-6 have been determined to recite allowable subject matter. Claims 8 and 9 remain rejected under 35 USC §112, first and second paragraphs. The Office Action also indicates that claims 8 and 9 are objected to because their syntax could be improved.

The claims recite a genus of isolated nucleic acids which are at least 96% identical to SEQ ID NO:1 which encodes a simian ORL-1 receptor protein that binds nociceptin. The claims also recite a variant of SEQ ID NO:2 as well as methods of screening compounds for ORL1 activity.

### **Claim Amendments**

Please amend claims 8 and 9. Please add New claims 13 and 14.

### **The Objections to Claims 8 and 9 Have Been Obviated**

The objection to claim 8 has been obviated by adopting the Examiner's suggestion to replace the phrase "one or between 2 and 6," with the phrase "fewer than 7." The Office Action indicates that this change can be made "without adding new matter" (Office Action, page 2) and refers Applicants to a new matter rejection, made for the first time in the Office Action dated January 13, 2009.

For the reasons, discussed more fully below, Applicants disagree with the finding that the specification as filed did not include support for the limitation "one or between 2 and 6." However, in the interest of advancing the allowance of the subject matter under examination in this application, Applicants have amended the claim 8, and the relevant portion of claim 9 (part ( c), step 2) to improve its syntax and clarity.

The objection to the preamble of claim 9 has been obviated by adopting the Examiner's suggested claim language. As amended, claim 9 now recites (in relevant part): "A method of evaluating a compound. . ."

No new matter has been added by way of the above-described claim amendments.

**The Rejection of Claims 3, 6, 8 and 9 Under 35 USC 112, First and Second Paragraphs Have Been Withdrawn**

Applicants acknowledge that the rejection of claims 3, 6, and 9 under 35 USC 112, first paragraph has been withdrawn in view of Applicant's amendments of the claims to recite a functional limitation and use of the term "isolated."

The rejection of claims 8 and 9 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment replacing the phrase "ORL1 activity," with a specific activity (i.e., "binds nociception").

**The Rejection of Claims 8 and 9 Under 35 USC §112, First Paragraph Have Been Obviated**

Claims 8 and 9 are rejected under 35 USC §112 first paragraph as failing to comply with the written description requirement.

The Office Action indicates that claims 8 and 9 recite contain subject matter which was not described in the specification in a such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8 and 9 were previously amended (amendment filed 8/1/2008) to recite the phrase "one or between 2 and 6" to describe a genus of mutant (or variant) simian ORL protein sequences comprising amino acid substitutions, deletions, additions or insertions. The subsequent Office Action (mailed September 19, 2008) did not object to the recitation of this phrase. However, the present Office Action indicates that "it has since been determined that no support is found for this limitation in the specification" (Office Action, page 3), and "therefore, this is a new matter rejection."

For the record, Applicants disagrees with the Examiner's statement that "no support is found for the limitation in the specification." This is based on the disclosure provided in paragraph 32 of the application which clearly indicates that:

The invention encompasses a protein having the amino acid sequence listed as SEQ ID NO: 2 or a mutant thereof. As such mutants there may be mentioned proteins consisting of the amino acid sequence listed as SEQ ID NO: 2 with a substitution, deletion or insertion of **one or between 2 and 6 amino acids** (emphasis added), . . .

Applicants' position is also supported by the Examiner's comment in the above-referenced September 19<sup>th</sup> Office Action in which the Examiner stated:

No rejection of Claims 8 and 9 is being made under 35 USC 112, first paragraph, with regard to the phrase "one, or between 2 and 6 amino acids" because the Examiner was "interpreting the term 'with' as closed language, meaning that the protein can have no more than 6 alterations" (Page 4, September 19<sup>th</sup> Office Action).

Accordingly, Applicants disagree with the finding that the specification of the instant application does not support a claim amendment which introduces the phrase "one, or between 2 and 6" into the text of claims 8 and 9. However, claims 8 and 9 have been amended to recite the alternative limitation "fewer than 7," which the Examiner has indicated can be added to the claim set under examination "without adding new matter" (Office Action, page 2).

Applicants have submitted two newly filed claims which have been written to capture alternative embodiments of the simian ORL1 proteins of the invention.

Based on the explanation provided above to traverse the new matter rejection, Applicants are of the opinion that claim 13 is supported by the disclosure provided in the specification.

Applicants are of the opinion that the subject matter of Claim 14 is supported by the specification based on the Examiner's determination that the prior art does not teach nucleic acids with an overall sequence identity of 96% or greater. Based on this finding, it follows that a protein which binds nociceptin and which is encoded by the novel, nucleic acid sequences of the invention are also patentable.

In light of the above-described claim amendments, Applicants respectfully request that the outstanding rejection of claims 3, 6 and 9 Under 35 USC §112, first paragraph be reconsidered and withdrawn.

#### **The Rejection of Claims 9 Under 35 USC §112 Second Paragraph Has Been Obviated**

Claim 9 is rejected under 35 USC, second paragraph, as being incomplete for omitting essential steps. The Office Action indicates that the alleged omissions amount to a gap between the steps, and that the claims should be amended to recite "a conclusion step stating what the desired endpoint or outcome of the method is" (Office Action, page 3).

Applicants have amended Claim 9 to recite the language suggested by the Examiner. More specifically, part (a), step 3 has been amended to include phrase "wherein specific binding of the test compound identifies it as an ORL1 ligand." Claim 9, part (b), step 4 has been amended to

recite the step "wherein a change in activity of the transducer in the presence of the compound indicates that the compound is a modulator of ORL1 activity."

Applicants have also amended part (c) step 2) to recite a conclusion step be amending the element to read as follows:

detecting a change in binding activity of nociceptin to the protein caused by the contact between the protein and the test compound, wherein a change in binding activity in the presence of the compound indicated that the compound is an agonist or an antagonist for ORL1.

In light of the above-described claim amendments, Applicants respectfully request that the outstanding rejection of claim 9 Under 35 USC §112, second paragraph be reconsidered and withdrawn.

### Summary

For the reasons set forth hereinabove, Applicants respectfully believe that all of the pending claims are in condition for allowance and request that the Examiner reconsider and withdraw the remaining claim objections and rejections. Applicants earnestly solicit a Notice of Allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

Respectfully submitted,

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